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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,024	05/15/2007	Elzbieta Mietkiewska	PAT 989W-2	1829

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BORDEN LADNER GERVAIS LLP
Anne Kinsman
WORLD EXCHANGE PLAZA
100 QUEEN STREET SUITE 1100
OTTAWA, ON K1P 1J9
CANADA

EXAMINER	
KUMAR, VINOD	
ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
09/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipinfo@blgcanada.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,024	MIETKIEWSKA ET AL.	
	Examiner	Art Unit	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/2010 has been entered.

Status of objections and rejections

2. Claims 25-43 are pending. Claims 1-24 are cancelled. Accordingly, claims 25-43 are examined on merits in the present Office action.

3. Objection to claim 27 is withdrawn in light of claim amendment filed in the paper of 6/2/2010.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of claims 41-43 under 35 U.S.C. 112, second paragraph is withdrawn in light of claim amendment filed in the paper of 6/2/2010.

Election/Restrictions

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 41 is objected to because of the following informalities:

Claim 41 is objected for having improper article before "plant as defined" in line 1. It is suggested to change "a" to –the-- or --said--.

This objection has been necessitated due to the claim amendment filed in the paper 6/2/2010.

Claim Rejections - 35 USC § 103

8. Claims 25-43 remain rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. (CA 2,203,754 (WO 96/13582), Issued May 9, 1996) in view of Jaworski et al. (US Patent Publication No. 20020049994, Published April 25, 2002) for the reasons of record stated in the Final Office action mailed 4/1/2010.

James et al. teach polynucleotide sequences from both the *Arabidopsis* FAE1 gene and *B. napus* FAE1 gene. The reference further teaches DNA constructs comprising the polynucleotide sequences that are used to modify FAE1 gene expression and thereby modulating fatty acid content in plant organs, particularly seeds. The reference further teaches transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence taught in the reference. The reference also teaches the use of said DNA construct in broad range of plants including *Linum* (flax), *Simondsia* and *Limnathes*. The reference also teaches that FAE1 polypeptide may also be expressed in a microorganism host, such as bacteria or yeast. The reference also teaches that overexpressing FAE1 gene in a seed increases the proportion of C20 or greater fatty acids (including erucic acid content) in said seed. The reference also teaches extracting or obtaining oil from said seeds. See in particular, page 8, line 21 through page 9, line 3; page 10, lines 26-27; claims 1-26.

James et al. do not teach *Crambe* fatty acid elongase as set forth in instant SEQ ID NO: 24.

Jaworski et al. teach a nucleic acid sequence encoding a fatty acid elongase 1 polypeptide of SEQ ID NO: 34 having 97% sequence identity to instant SEQ ID NO: 24. The reference further teaches DNA

constructs comprising said polynucleotide sequence to modulate fatty acid content in plant organs, particularly seeds. The reference further teaches transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence taught in the reference. The reference also teaches the use of said DNA construct in broad range of plants including *Crambe abyssinica,* flax and *Brassica sp.* The reference also teaches that said polypeptide may also be expressed in a microorganism host, such as bacteria or yeast to increase C20 or C22 fatty acid content. The reference also teaches that overexpressing said polypeptide in a seed increases the proportion of C20 or greater fatty acids (including erucic acid content) in said seed. The reference also teaches extracting or obtaining oil from said seeds. See in particular, claims 1-23; paragraphs 0001-0138; examples 1-4.

Given the use of elongase enzymes from *Arabidopsis*, *Brassica* and other plant species, including the one taught by Jaworski et al. share identical enzymatic activities for modulating fatty acid content in a plant as asserted by James et al., it would have been obvious and within the scope of an ordinary skill in the art to have used any fatty acid elongase gene including the one from Jaworski et al. *Crambe abyssinica* plant as a part of normal design procedure and regardless of its source in modulating fatty acid content in a plant, and thus arrive at the claimed invention with a reasonable expectation of success.

Given that Jaworski et al. polynucleotide sequence encoding FAE1 (SEQ ID NO: 34) is highly homologous to instant SEQ ID NO: 25 encoding FAE1 of SEQ ID NO: 24, and which exhibits elongase activity in increasing C20 or greater fatty acid proportion (including erucic acid content) in transgenic plant cell, it would have been obvious and within the scope of an ordinary skill in the art at the time the invention was made to isolate and identify claimed nucleotide sequences (variants of Jaworski et al. polynucleotide sequence encoding SEQ ID NO: 34) based on the polynucleotide sequence encoding Jaworski et al. SEQ ID NO: 34 by applying conventional methodologies of variant DNA isolation which had a reasonable expectation of success.

It would have been prima facie obvious, and within the scope of an ordinary skill in the art at the time the claimed invention was made to choose from a finite number of predictable variants of a nucleotide sequence encoding Jaworski et al. polypeptide of SEQ ID NO: 34 with a reasonable expectation of success of producing transgenic plants having increased C20 or greater proportion of fatty acids, including increase in erucic content.

See the recent Board decision *Ex parte Smith*, -- USPQ2d --, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). KSR forecloses the argument that a **specific** teaching, suggestion or motivation is required to support a finding of obviousness.

Thus, the claimed invention as a whole is prima facie obvious over the teachings of the prior art.

Response to Applicant's arguments:

Applicant primarily argues that instantly claimed invention involves over-expressing *Crambe* FAE gene in transgenic plants which exhibit 1.5 fold increase in erucic acid 22:1, whereas James et al. FAE gene from *Arabidopsis* or *Brassica* when overexpressed in a transgenic plant results 1.1 to 1.25 fold increase in erucic acid 22:1. Applicant cites Taylor's declaration filed in the response of 6/2/2010 to support these arguments. Applicant refers such difference in the increase of erucic acid 22:1 as "superior results" which would not have been obvious to one of ordinary skill in the art. Applicant further alleges that Jaworski et al. SEQ ID NO: 34 is only 92% identical to instant SEQ ID NO: 24 and thus obviousness rejection is improper (response, pages 7-11 and declaration filed under 37 CFR § 1.132).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

It is noted that FAE gene isolated from *Arabidopsis*, *Brassica* or other plant species encode elongase protein which exhibits the activity to increasing erucic acid 22:1 content in a plant. The encoded FAE protein from *Arabidopsis*, *Brassica* or other plant species catalyze the same reaction to increase erucic acid 22:1. James et al. teachings clearly assert that as discussed above in the rejection.

Applicant's arguments are not persusaive to suggest that instant SEQ ID NO: 24 is 92% identical to Jaworski et al. SEQ ID NO: 34. It is maintained that instant SEQ ID NO: 24 has 97% identity to Jaworski et al. SEQ ID NO: 34. Applicant's attention is drawn to sequence search results as shown below:

Query: Instant SEQ ID NO: 24; Db: Jaworski et al. SEQ ID NO: 34

```
Query Match             97.0%;  Score 2552;  DB 2;  Length 506;
Matches  487;  Conservative    8;  Mismatches   11;  Indels    0;  Gaps    0;

Qy          1 MTSINVKLLYHYVITNLFNLCFFPLTAIVAGKASRLTIDDLHHLYYSYLQHNVITIAPLF 60
              |||||||||||||||||||||||||||||||| |||||||||||||||:|||||||
Db          1 MTSINVKLLYHYVITHLFNLCFFPLTAIVAGKAYRLTIDDLHHLYYSYLQHNLITIAPLF 60

Qy         61 AFTVFGSILYIVTRPKPVYLVEYSCYLPPTQCRSSISKVMDIFYQVRKADPFRNGTCDDS 120
              |||||||:||| ||||||||||||||||| |||||||||||||||||||||||||||||
Db         61 AFTVFGSVLYIATRPKPVYLVEYSCYLPPTHCRSSISKVMDIFYQVRKADPSRNGTCDDS 120

Qy        121 SWLDFLRKIQERSGLGDETHGPEGLLQVPPRKTFAAAREETEQVIVGALKNLFENTKVNP 180
              ||||||||||||||||||||||||||||||||||||||||||||:|||:|||:|| |||
Db        121 SWLDFLRKIQERSGLGDETHGPEGLLQVPPRKTFAAAREETEQVIIGALENLFKNTNVNP 180

Qy        181 KDIGILVVNSSMFNPTPSLSAMVVNTFKLRSNVRSFNLGGMGCSAGVIAIDLAKDLLHVH 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 KDIGILVVNSSMFNPTPSLSAMVVNTFKLRSNVRSFNLGGMGCSAGVIAIDLAKDLLHVH 240

Qy        241 KNTYALVVSTENITYHIYAGDNRSMMVSNCLFRVGGAAILLSNKPRDRRRSKYELVHTVR 300
              ||||||||||||||||||||||||||||||||||||||||| ||||||||||||||||||
Db        241 KNTYALVVSTENITYHIYAGDNRSMMVSNCLFRVGGAAILLSNKPGDRRRSKYELVHTVR 300

Qy        301 THTGADDKSFRCVQQGDDENGKTGVSLSKDITEVAGRTVKKNIATLGPLILPLSEKLLFF 360
              |||||||||||||||||||| ||||||||:|||||||||||||||||||||||||||||
Db        301 THTGADDKSFRCVQQGDDENGKIGVSLSKDITDVAGRTVKKNIATLGPLILPLSEKLLFF 360

Qy        361 VTFMAKKLFKDKVKHYYVPDFKLAIDHFCIHAGGRAVIDVLEKNLGLAPIDVEASRSTLH 420
              |||| |||||||:|||||||||||||||||||||||||||||| ||||||||||||||||
Db        361 VTFMGKKLFKDKIKHYYVPDFKLAIDHFCIHAGGRAVIDVLEKNLALAPIDVEASRSTLH 420

Qy        421 RFGNTSSSSIWYELAYIEAKGRMKKGNKVWQIALGSGFKCNSAVWVALSNVKASTNSPWE 480
              ||||||||||||||||||||||||||||||||||||||||||||||:||||||||||||
Db        421 RFGNTSSSSIWYELAYIEAKGRMKKGNKVWQIALGSGFKCNSAVWVALMNVKASTNSPWE 480

Qy        481 HCIDRYPVKIDSDSAKSETRAQNGRS 506
              |||||||||||||| ||||| |||||
Db        481 HCIDRYPVKIDSDSGKSETRVQNGRS 506
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It is maintained that it would have been obvious and within the scope of an ordinary skill in the art to have used any fatty acid elongase gene including the one from Jaworski et al. to arrive at the claimed invention with a reasonable expectation of success.

It is maintained that *Crambe abyssinica* plant as a part of normal design procedure and regardless of its source in modulating fatty acid content in a plant, and thus arrive at the claimed invention with a reasonable expectation of success.

It is further maintained that given that Jaworski et al. polynucleotide sequence encoding FAE1 (SEQ ID NO: 34) is highly homologous to instant SEQ ID NO: 25 encoding FAE1 of SEQ ID NO: 24, and which exhibits elongase activity in increasing C20 or greater fatty acid proportion (including erucic acid content) in transgenic plant cell, it would have been obvious and within the scope of an ordinary skill in the art at the time the invention was made to isolate and identify claimed nucleotide sequences (variants of Jaworski et al. polynucleotide sequence encoding SEQ ID NO: 34) based on the polynucleotide sequence encoding Jaworski et al. SEQ ID NO: 34 by applying conventional methodologies of variant DNA isolation which had a reasonable expectation of success.

It is further maintained that it would have been prima facie obvious, and within the scope of an ordinary skill in the art at the time the claimed invention was made to choose from a finite number of predictable variants of a nucleotide sequence encoding Jaworski et al. polypeptide of SEQ ID NO: 34 with a reasonable expectation of success of producing transgenic plants having increased C20 or greater proportion of fatty acids, including increase in erucic content.

Applicant's argument to suggest that the present obviousness analysis involves to vary all parameters or try each of numerous possible choices to arrive at the instantly claimed invention is not persuasive. In the present obviousness analysis, there are finite number of variants, all of which exhibit same enzymatic activity to produce the erucic acid 22:1 product. Contrary to Applicant's allegations, there is nothing unpredictable as it was well known in the prior art that FAE gene isolated from different plant source would perform identical function of increasing erucic acid 22:1 upon expression in a plant.

Applicant's argument to suggest that "obvious to try" situation occurs only when prior art gave general guidance to explore the claimed invention is not persuasive. It was well known in the cited prior

art that expressing a FAE gene in a plant increases erucic acid 22:1 fatty acid in said plant, and source of FAE gene would not have produced unexpected or surprising results.

It is also important to note that the issue is not whether instant SEQ ID NO: 24 produces 1.5 fold increase in erucic acid 22:1 compared to James et al. FAE proteins which produce 1.1 to 1.25 fold increase in erucic acid 22:1. Rather the issue is whether it was obvious to one of ordinary skill in the art to have overexpressed a FAE gene in a plant to increase erucic acid 22:1 to arrive at the claimed invention. Based on the teachings of James et al. and Jaworski et al. as discussed above, it was well known in the prior art to express a FAE gene encoding an elongase in a plant to increase erucic acid 22:1 in the plant.

Even a difference of less than one fold cannot be termed as a superior result as argued by the Applicant. Additionally, it was well known in the art of plant transformation to expect small differences in the levels of transgenic protein in the segregating transgenic progenies. Such differences can also be attributed to different transformation events rather than to the source of FAE protein.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, it would have been obvious and within the scope of an ordinary skill in the art to have arrived at the time the claimed invention with a reasonable expectation of success by combining the teachings of the prior art as discussed above.

It is also noted that features upon which applicant relies (i.e., 1.5 fold increase in erucic acid 22:1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, it would have been obvious and within the scope of an ordinary skill in the art to have arrived at the time the claimed invention with a reasonable expectation of success by combining the teachings of the prior art as discussed above.

Accordingly, the rejection is maintained.

Conclusions

9. Claims 25-43 remain rejected.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Primary Examiner, Art Unit 1638